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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,947	12/12/2005	James N. Petitte	297/204 PCT/US	1436

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,947	PETITTE ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-10 and 58-71* is/are pending in the application.

4a) Of the above claim(s) *61-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-10,58-60 and 69-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 5, 6 and 11-57 have been canceled. Claims 1-4, 7-10 and 58-71 are pending.

Applicant's arguments filed 12-10-10 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Consider: A method of decreasing/inhibiting primordial germ cells (PGC) numbers/development in an avian embryo by immunizing a female bird with DAZL, obtaining an egg comprising an embryo from the female bird, wherein the embryo has decreased number of PGCs. Please point to support for each step in the specification as originally filed upon amendment.

Election/Restrictions

While support for administering VASA and DAZL as in claim 62 is found on pg 54 in Table 1 (chicken #548, for example), claims 61 and 62 submitted 10-29-09 require administering at least two antigens, which is independent or distinct from the invention originally claimed for the following reasons: the species election originally made on 5-16-07 required election of one antigen for consideration, and the claims did not claim administering at least two antigens. Administering DAZL was elected without traverse. In addition, claims 63-68 are drawn to producing a chimeric avian using donor PGCs from the same or different avian species as the recipient embryo, which is equivalent to

Group III and IV in the restriction requirement sent 5-16-07: however, applicants elected Group II without traverse in the response filed 6-18-07.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-68 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Similarly, claims 69-71 submitted 5-24-10 require administering "an amount of antigen…" which encompasses administering two or more antigens, which is independent or distinct from the invention originally claimed for the following reasons: the species election originally made on 5-16-07 required election of one antigen for consideration, and the claims did not encompass administering two or more antigens. Administering DAZL was elected without traverse. Claims 69-71 will be examined only as they relate to the elected subject matter; administering one antigen – DAZL.

Applicants' request for an additional search is noted but is inappropriate at this time. Claims 1-4, 7-10, 58-60 and 69-71 remain under consideration as they relate to decreasing PGC numbers/development using on antigen - DAZL.

Claim Rejections - 35 USC § 112

New Matter

Claims 70 and 71 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection regarding the phrase "antigen associated with primordial germ cell development" in claims 1, 7 and 69 has been withdrawn in view of support on pg 3, line 18, and pg 11, line 27, through pg 12, line 9.

The rejection regarding the phrase "an amount of antigen associated with primordial germ cells sufficient to generate…" in new claim 69 has been withdrawn in view of support on pg 3, line 18, and pg 11, line 27, through pg 12, line 9.

The range in claim 70 ("the amount of antigen ranges from about 50-200 µg") remains new matter. Applicants' point to pg 52, lines 8-16, which discusses a secondary immunization with "50-100 µg of conjugated peptide + TMA", which in no way implies an initial immunization with an antigen associated with PGC development as now claimed or the range of 50-200 µg as now claimed. Applicatns point to pg 56, lines 3-17, which does not contemplate the antigens associated with PGC development were administering in the range of 50-200 µg as claimed.

Claim 71 as newly amended is rejected under new matter. Support has not been provided and none can be found in the specification as originally filed.

Enablement

Claims 1-4, 7-10 and 69-70 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 71 has been withdrawn from the rejection because it is limited to DAZL.

Claim 1 is drawn to a method for decreasing primordial germ cell (PGC) numbers in an avian embryo, the method comprising immunizing a female bird with an antigen associated with primordial germ cell development, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies that bind to the antigen expressed by an avian embryo present within the egg to decrease endogenous PGC numbers in the avian embryo.

Claim 7 is drawn to a method for inhibiting primordial germ cells (PGC) development in an avian embryo, the method comprising immunizing a female bird with an antigen associated with primordial germ cell development, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies specific for the antigen to bind to the antigen expressed by an avian embryo within the egg to inhibit development of PGCs in the avian embryo.

Claim 69 is drawn to a method for decreasing primordial germ cells numbers in an avian embryo, the method comprising immunizing a female bird with an amount of antigen associated with primordial germ cell development sufficient to generate an antibody response in the bird whereby an egg produced by the female bird comprises antibodies that bind to the antigen expressed by an avian embryo present within the egg, wherein endogenous Primordial Germ Cell numbers in the avian embryo are decreased.

It is noted that claims 1, 7, 58 and 69 encompass decreasing PGCs in an avian embryo without repopulating the embryo with donor PGCs and without obtaining a chimeric avian. The embryos are placed in an incubator until Stage 14-17 (H&H) which is about 50-64 hours. Recipient embryos can then be injected with donor PGCs at stage 14-17 (H&H) (pg 57, lines 7-14). The recipient embryos can be shipped for use at stage 14-17 (H&H).

The specification does not enable using any antigen “associated” with PGC development as broadly claimed in claims 1, 7 and 69 which require administering “antibodies specific for the antigen to bind to the antigen expressed by an avian embryo within the egg to thereby decrease endogenous PGC numbers". The specification defines antigens “associated” with PGC development as any antigen expressed by a PGC (paragraph bridging pg 11-12). The claims encompass antigens associated with PGCs and any other cells; the claims encompass antibodies attacking the antigen expressed on PGCs and anywhere else in the avian embryo. For example, the claim now encompasses using a histocompatibility marker present on all cells (and also “associated” with PGCs) as the antigen. The claims also encompass binding the antibodies to antigen anywhere in the embryo. Pg 29 states “antibodies that bind antigens associated with PGCs are deposited in the yolk of eggs produced by female birds immunized with the antigen.” Pg 30-31 discusses modulating PGC development in an avian embryo. The examples, however, are limited to using antigens that are specific to PGCs. The specification does not teach how to use the method claimed when the antigen is “associated with” PGCs and other embryonic cells as now broadly

claimed. Without using antigens that are specific to PGCs, the antibodies obtained in the egg would destroy all tissues expressing the antigen and prevent survival of the embryo. Applicants fail to adequately teach how to use the method claimed with any antigen “associated with” PGCs that would also destroy tissues other than PGC in the embryo. The art at the time of filing and the level of skill in the art at the time of filing provide no guidance in this regard. As such, it would have required those of skill undue experimentation to determine how to administer any antigen “associated with” PGCs such that destruction of non-PGC tissues in the embryo is prevented and survival of the embryo occurs.

Response to arguments

Applicants argue the specification defines antigens “associated with PGCs.” Applicants argue a list of exemplary antigens "associated with PGCs” are on pg 11-12. Applicants' argument is not persuasive. The definition on pg 11-12 is extremely broad, i.e. any antigen expressed by a PGC. However, antigens that make antibodies that specifically decrease PGC numbers without generically decreasing cells in the embryo and without destroying the embryo are essential to the invention. Not all antigens expressed by PGCs as broadly defined on pg 11-12 would decrease PGC numbers or inhibit PGC development as claimed for reasons cited above in the body of the rejection. The number of antigens expressed by PGCs that are not specific to PGCs outweighs the number of antigens that are specific to PGCs.

Applicants’ other comments under enablement are noted but do not appear to contain any other arguments.

Indefiniteness

Claims 1-4, 7-10, 58-60 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 69 regarding the phrase "the female bird" has been withdrawn.

The rejection of claim 69 regarding the phrase "that bind to the antigen" has been withdrawn in view of the amendment.

The metes and bounds of what applicants consider "sufficiently high concentration of antibodies that bind to the antigen expressed by an avian embryo within the egg, wherein endogenous PGC numbers [or development] in an avian embryo are decreased [inhibited]" (claims 1, 7 and 58) remain unclear. The specification does not teach how to determine whether PGCs numbers decrease without sacrificing the avian (pg 54, lines 4-6, "Stage 27 (H&H) embryos were sacrificed"). The specification does not teach how to use the assay on pg 54 when making chimeric avians (the sole disclosed use for the method claimed). The concentration of antibodies required to decrease the number or development of PGCs and maintain a viable embryo is not set forth in the specification or the art at the time of filing. Applicants have not provided an assay for those of skill to determine when the amounts of antibodies were "sufficiently high" enough to decrease PGC numbers in an embryo that becomes a viable avian. Thus, those of skill would not be able to determine when the concentration of antibodies obtained was infringing on the claim

when making viable chimeric avians. Applicants have provided the amount of antigen that is sufficient to decrease PGC numbers, not the amount of antibody.

Response to arguments

Applicants argue they have provided ample guidance to determine how to assess PGC decreases in an avian embryo that had hatched. Applicants' argument is not persuasive. Applicants have not provided a means to determine how to determine that PGC numbers decrease in an avian embryo without sacrificing the embryo. Applicants have provided the amount of antigen that is sufficient to decrease PGC numbers, not the amount of antibody.

The art did not reasonable teach or suggest decreasing/inhibiting primordial germ cells (PGC) numbers/development in an avian embryo by immunizing a female bird with DAZL, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies that bind to DAZL expressed by an avian embryo present within the egg to decrease the number of PGCs in the avian embryo or inhibit the development of PGCs in an avian embryo present within in the egg.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner
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